# Administrative data to support randomised controlled trials: central venous catheters in paediatric intensive care

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# Context: opportunities for using admin data to support RCTs

| | |
|---|---|
| 1. Enhanced study design and recruitment<br><br>identify patient populations and derive event rates | 2. Efficient assessment of effectiveness<br><br>capturing patient characteristics and outcomes |
| 3. Determining generalisability of results<br><br>informing decisions on implementation by highlighting variation across units; allowing targeted improvement | 4. Monitor the scaling-up of interventions<br><br>detecting changes in the adoption of interventions |
| 5. Long-term follow up<br><br>re-activiating 'dormant' trials through linkage with admin data | |

Henry and Fitzpatrick. Liberating the data from clinical trials. BMJ 2015;351:h4601

# Background

CATheter Infections in CHildren

**Population:** children in intensive care

**Intervention:** heparin or antibiotic

central venous catheters (CVCs)

**Comparison:** standard CVCs

**Outcome:** hospital-acquired blood stream infection

# Background

CATheter Infections in CHildren

**Population:** children in intensive care

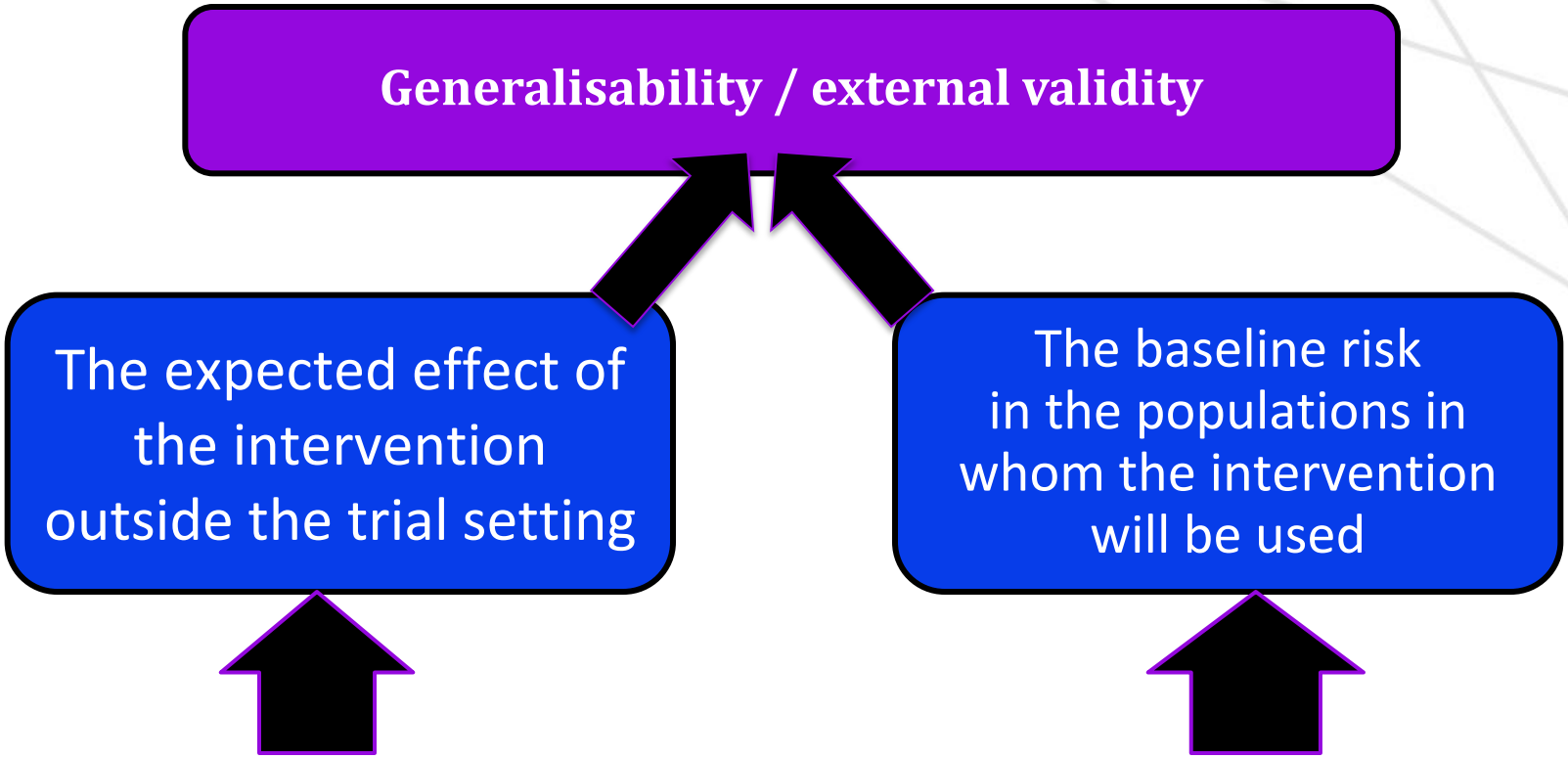
*Expected to require a CVC for at least 3 days*

But….

Would likely be used in all children

including those staying <3 days → lower infection risk

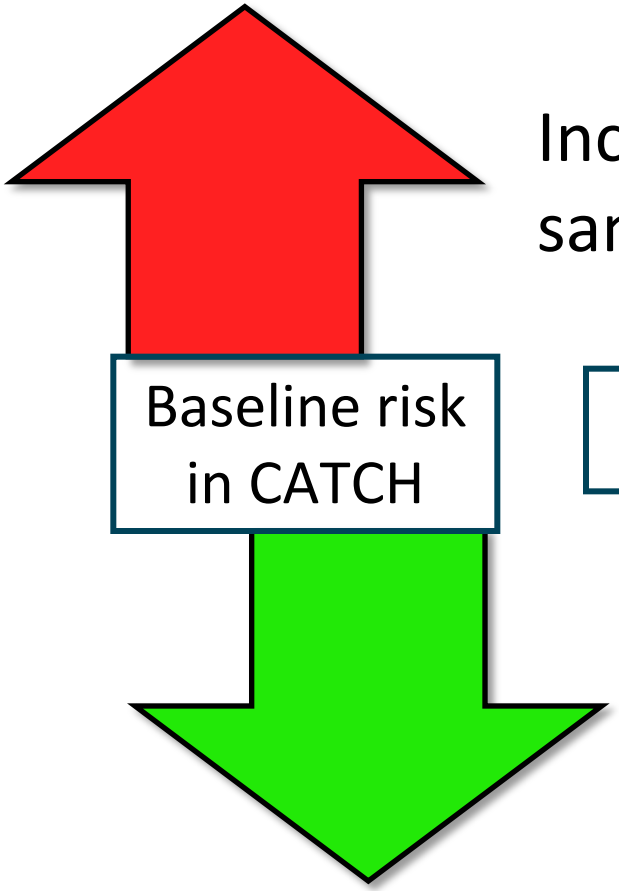
# Background




- pragmatic trial
- expect mechanisms to be the same

??

# Background

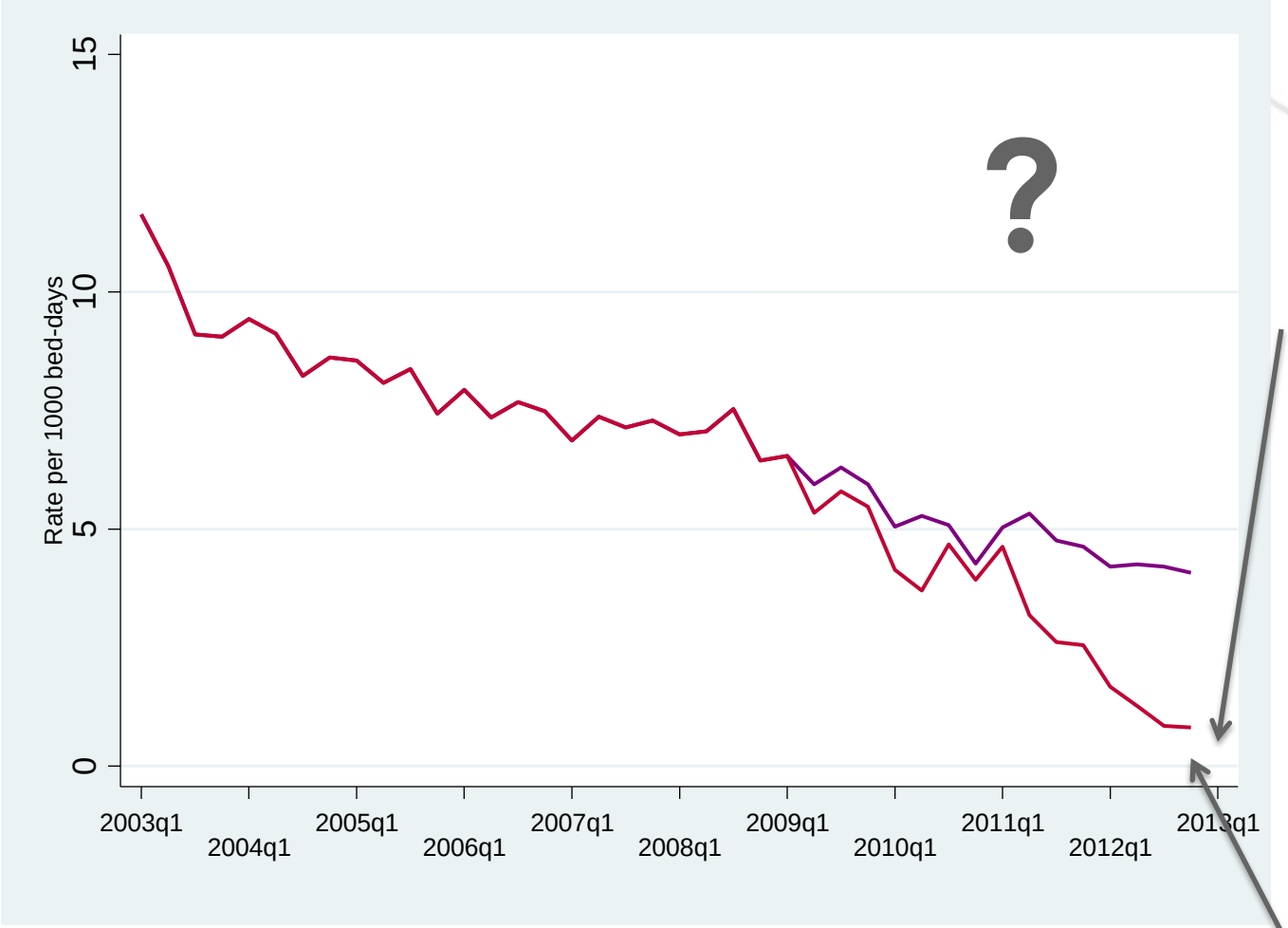



Increased sensitivity of blood sampling during CATCH

Administrative data

Improvements in infection control (CVC care bundle interventions)

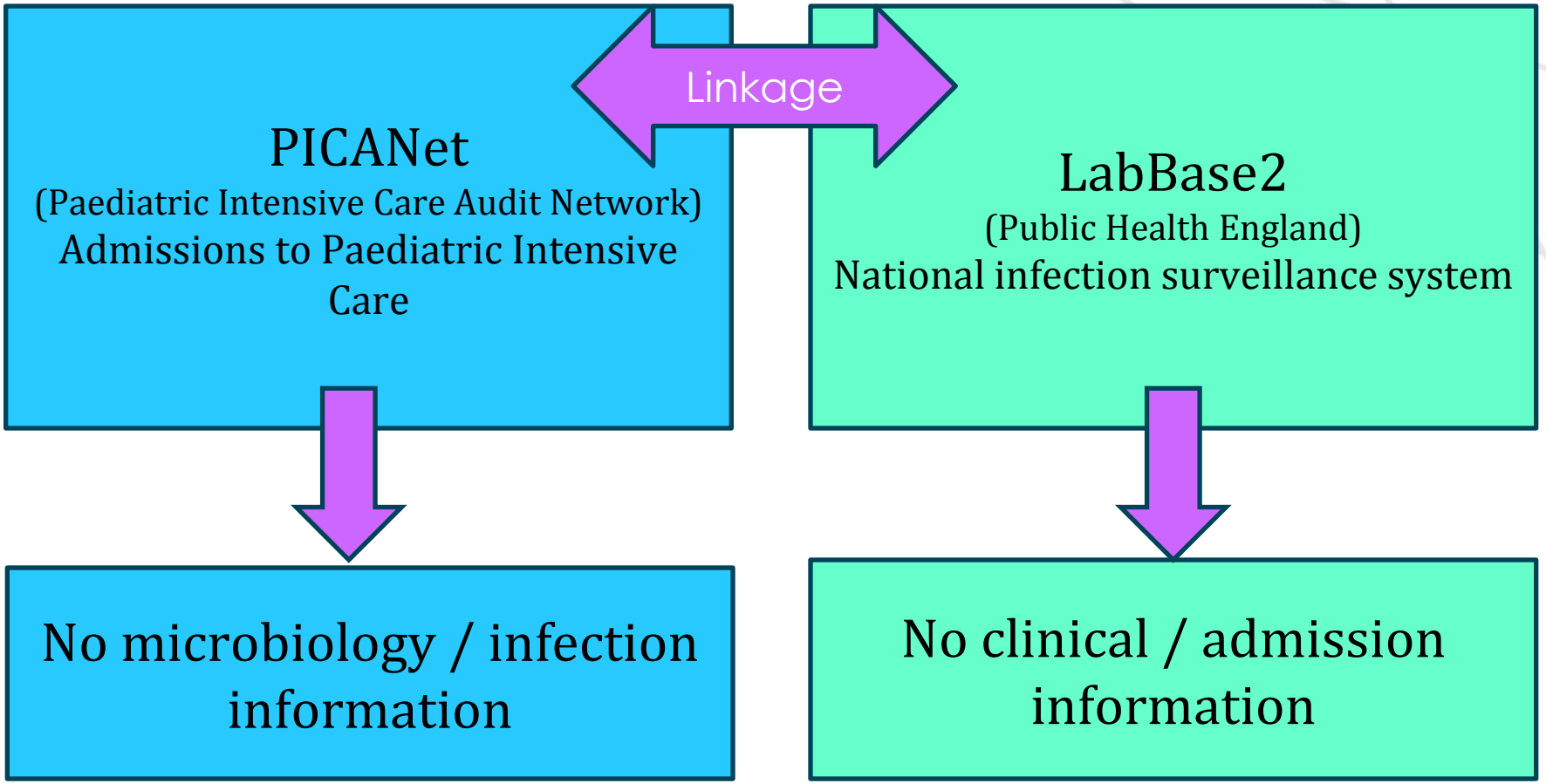
# Background




The lower the baseline risk, the lower the absolute number of infections avoided

Same expense, less benefit

# Methods



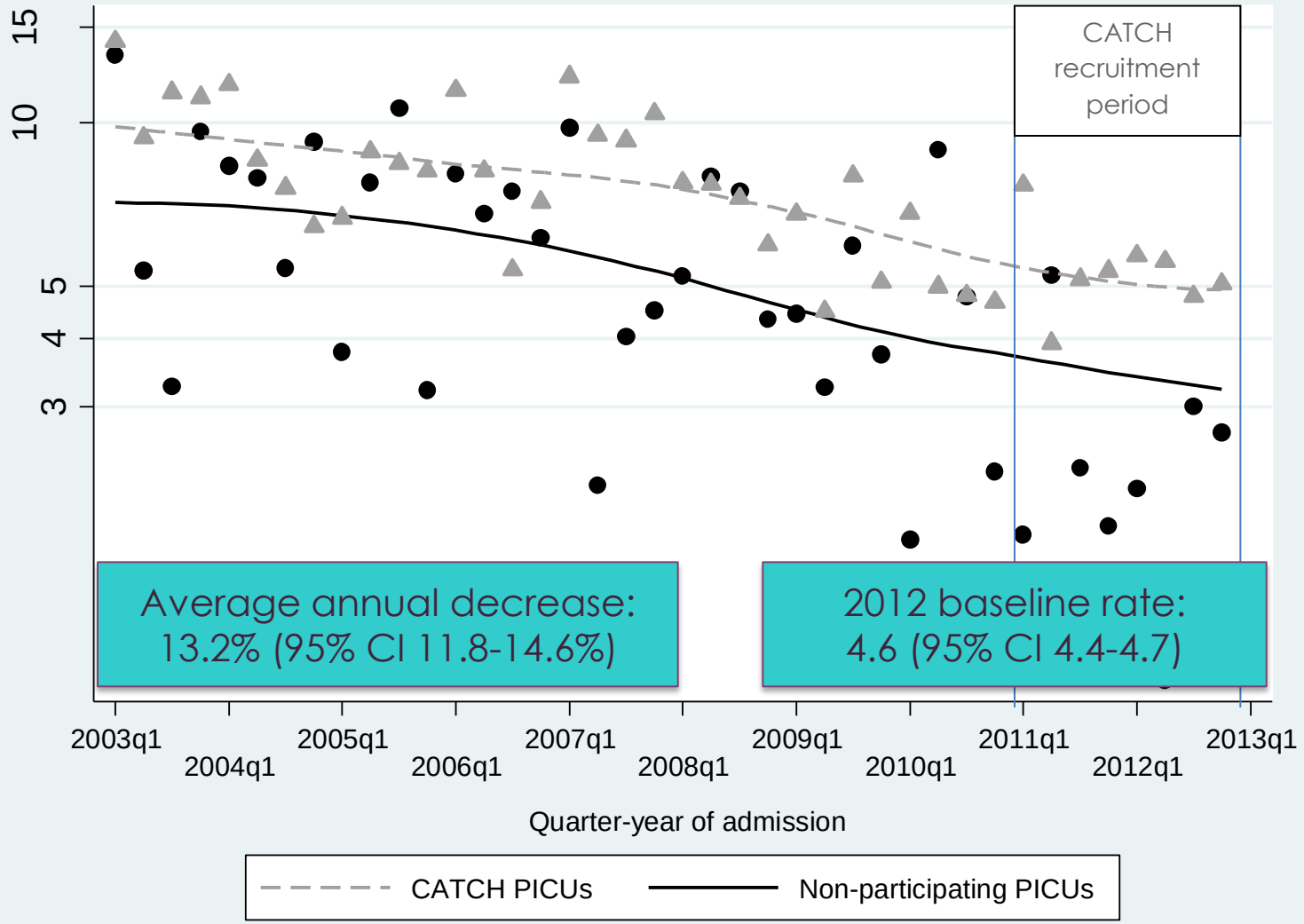

Harron et al. Linkage, evaluation and analysis of national electronic healthcare data. PLoS One 2013 doi:10.1371/journal.pone.0085278

# CATCH Results (*Lancet: in press*)

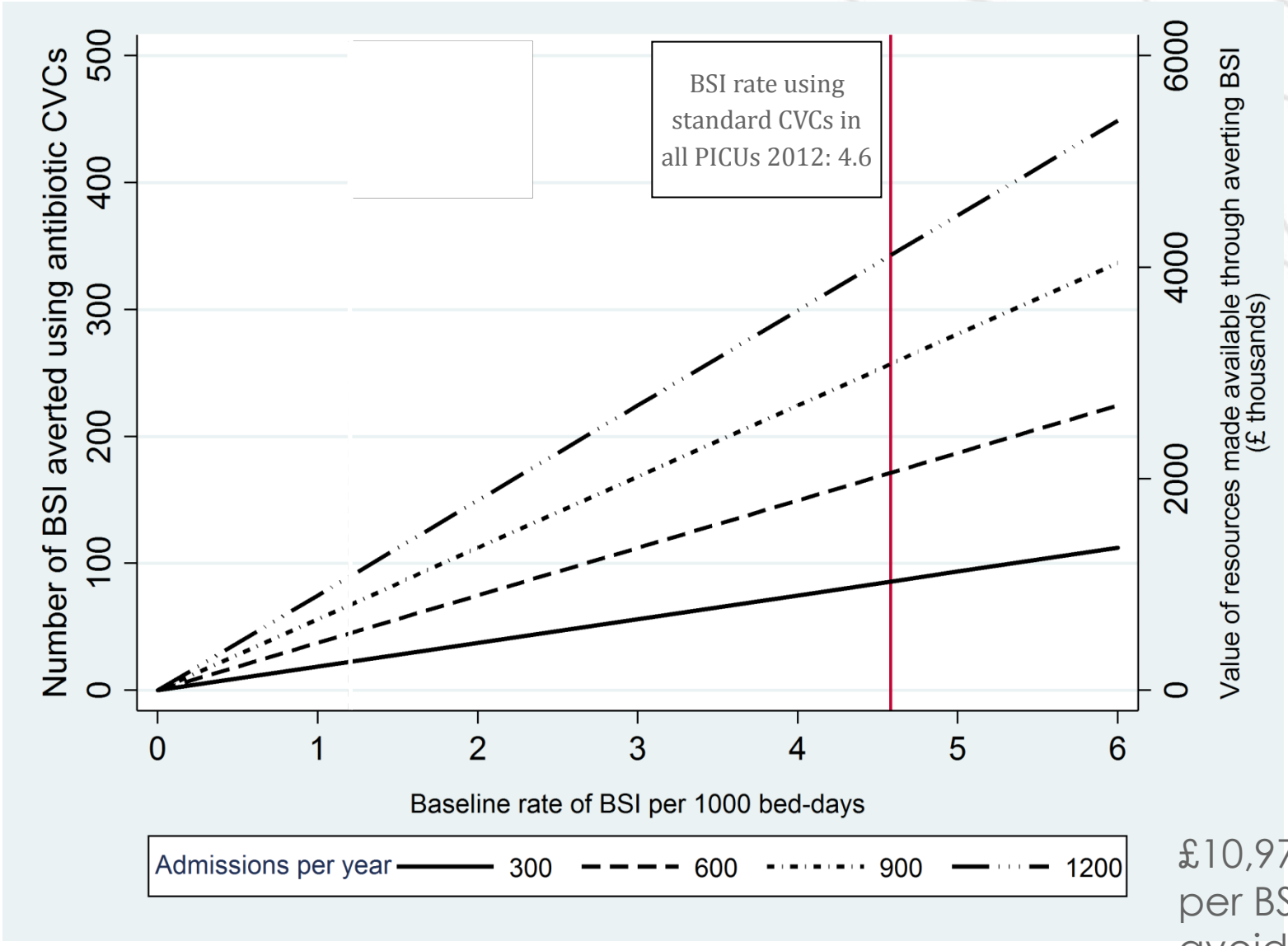
- 1485 children randomised to standard, antibiotic or heparin CVCs
- 42 bloodstream infections
- 8.2 (4.7-11.8) per 1000 bed-days in standard CVCs
- Antibiotic CVCs were superior to standard: RR 0.40 (0.17-0.97)
- £10,975 : value of resources associated with of each infection (economics analysis)
- Additional cost of impregnated CVC: £36


CATheter Infections in CHildren

# Generalisability Results

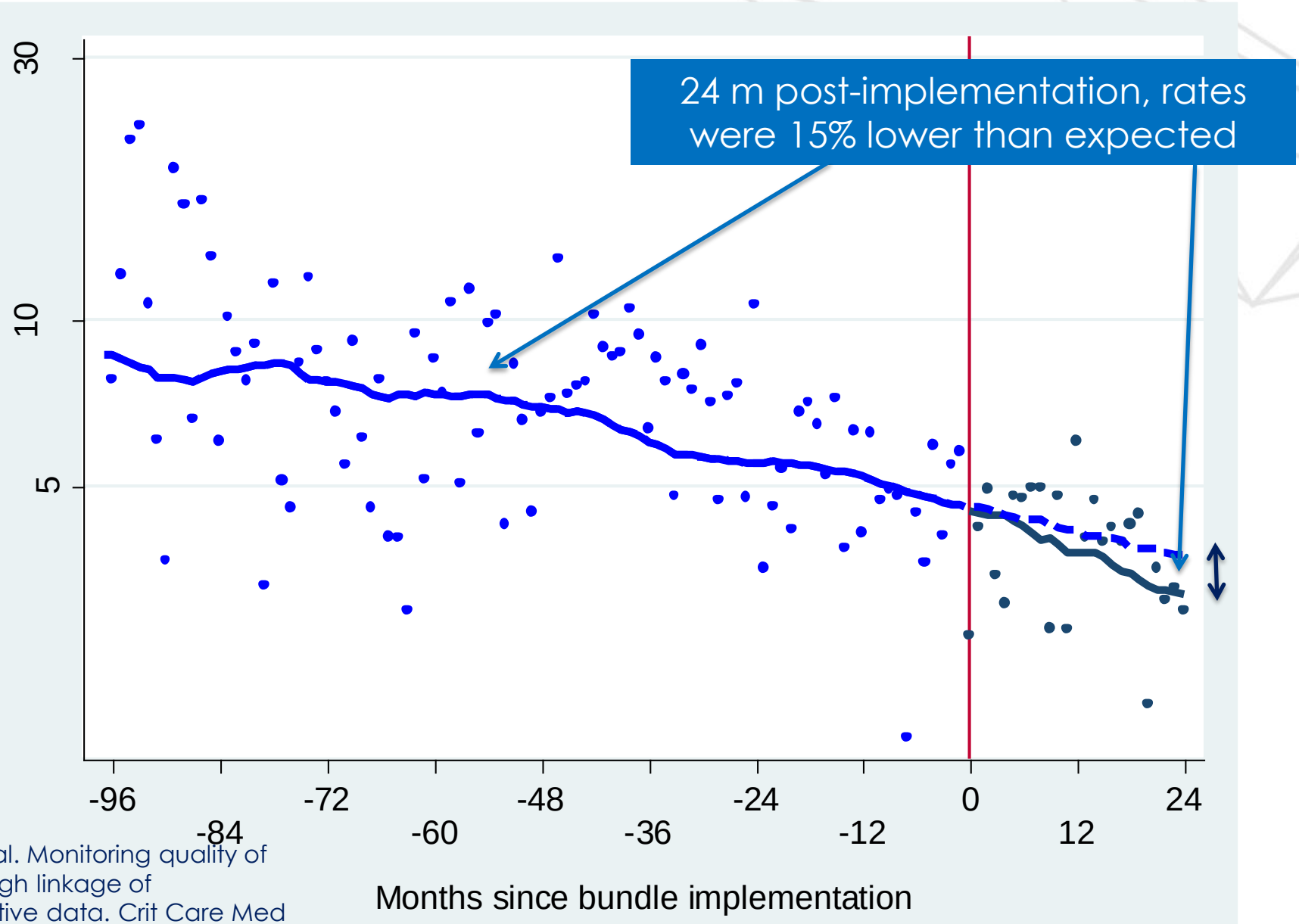


# Generalisability Results




£10,975 per BSI avoided

# Generalisability Results




Harron et al. Monitoring quality of care through linkage of administrative data. Crit Care Med 2015:43(5):1070

# Summary

- Administrative data provided context for CATCH trial:
  - BSI rates decreasing in all main clinical groups long before trial began or care bundles introduced
  - Implementation of CVC care bundles associated with a small but significant reduction in BSI rates
  - Antibiotic CVCs reduce risk of BSI by ~60%, even in context of low BSI rates
  - Benefits apply even for PICUs with BSI rates as low as 1.2 per 1000 bed days

# Conclusions

- Administrative data can support RCTs:
  - Estimating event rates for sample size calculations
  - Capturing trends pre- and post-intervention
  - Providing unit-specific baseline risks to inform purchasing decisions and allow targeted quality improvement
  - Monitoring implementation of effective interventions
  - Capturing long-term safety and effectiveness outcomes without attrition (dormant trials)
    - e.g. long-term neurological outcomes of neonatal infections

Harron et al. E-health data to support and enhance randomised controlled trials in the UK. Clin Trials 2015:12(2):180

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